



1644

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Saxon, et al. Docket No.: 39754-0672A  
Serial No.: 09/847,208 Group Art Unit: 1644  
Filing Date: May 1, 2001 Examiner: Nuynh, P.  
For: **FUSION MOLECULES AND TREATMENT OF IgE-MEDIATED ALLERGIC DISEASES**

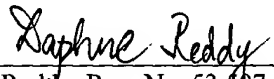
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## TRANSMITTAL

- ☒ Transmitted herewith are the following documents:
- (1) Transmittal;
  - (2) Supplemental Information Disclosure Statement;
  - (3) PTO Form 1449;
  - (4) Copies of 49 of cited references.
- ☒ The Commissioner is authorized to charge any required fees, or credit any overpayment to Deposit Account No. 08-1641.
- ☒ Attached is a postcard for date-stamped return as confirmation of receipt of these materials.

Respectfully submitted,

Date: August 14, 2003

  
Daphne Reddy, Reg. No. 53,507  
for  
Ginger R. Dreger, Reg. No. 33,055

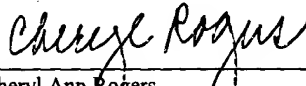
**HELLER EHRMAN WHITE & MCAULIFFE LLP**

**Customer No. 25213**  
275 Middlefield Road  
Menlo Park, CA 94025  
Telephone: (650) 324-7000  
Facsimile: (650) 324-0638

## CERTIFICATE OF MAILING (37 CFR 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: August 14, 2003

  
Cheryl Ann Rogers



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

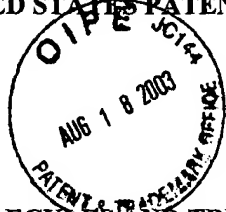
Applicant: Saxon, et al.

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**FUSION MOLECULES AND TREATMENT OF IgE-MEDIATED ALLERGIC DISEASES**



Docket No.: 39754-0672A

Group Art Unit: 1644

Examiner: Nuynh, P.

**SUPPLEMENTAL INFORMATION DISCLOSURE**  
**STATEMENT UNDER 37 C.F.R. §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- ☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --

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Date: August 12, 2003

*Cheryl Ann Rogers*  
Cheryl Ann Rogers

- ☐ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
- ☒ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; or
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$180.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ *Fee Authorization.* The Commissioner is authorized to charge any required fees, additional fees, or credit any overpayment to Deposit Account 08-1641 (Docket No. 39754-0672A).

Respectfully submitted,

Dated: August 12, 2003

By: 

Ginger R. Dreger  
Reg. No. 33,055

**HELLER EHRMAN WHITE & MCAULIFFE LLP**

**Customer No. 25213**

275 Middlefield Road

Menlo Park, CA 94025-3506

Telephone: (650) 324-7000

Facsimile: (650) 324-0638



<b>INFORMATION DISCLOSURE STATEMENT</b>			<b>ATTY. DOCKET NO.:</b> 39754-0672		<b>SERIAL NO.:</b> 09/847,208	
<b>PTO-1449</b>			<b>APPLICANT:</b> Saxon et al.			
			<b>FILING DATE:</b> May 1, 2001		<b>GROUP:</b> 1644	
<b>U.S. PATENT DOCUMENTS</b>						
<b>EXAMINER'S INITIALS</b>	<b>PATENT NO.</b>	<b>DATE</b>	<b>NAME</b>	<b>CLASS</b>	<b>SUBCLASS</b>	<b>FILING DATE</b>
	20030049237	3/13/03	Bannon, Gary A., et al.			
	20010053770	12/20/01	Thomas, David, et al.			
	20030077282	4/24/03	Bigler, Michael Eric, et al.			
	6,043,345	3/28/00	Saxon, et al.			
	5,563,250	5/13/94	Hylarides, Mark D., et al.			
	5,827,516	6/7/95	Urban, Robert Glen, et al.			
	5,811,265	7/26/93	Quertermous, Thomas, et al.			
	6,093,699	11/10/94	Sehon, Alec, et al.			
	5,965,605	10/12/99	Cheng, et al.			
	5,017,693	12/19/89	Hylarides, Mark D., et al.			
<b>FOREIGN PATENT DOCUMENTS</b>						
<b>EXAMINER'S INITIALS</b>	<b>PATENT NO.</b>	<b>DATE</b>	<b>COUNTRY</b>	<b>CLASS</b>	<b>SUBCLASS</b>	<b>TRANSLATION</b>
	WO 96/12740	05/02/96	EP			<input type="checkbox"/> YES <input type="checkbox"/> NO
	WO 95/26365	10/5/95	EP			<input type="checkbox"/> YES <input type="checkbox"/> NO
						<input type="checkbox"/> YES <input type="checkbox"/> NO
						<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>						
<input checked="" type="checkbox"/> Abdelilah, S.G., et al., "Molecular Characterization of the Low-Affinity IgE Receptor FcεRII/CD23 Expressed by Human Eosinophils", <i>Int. Immunol.</i> , 1998 Apr; 10(4):395-404.						
<input checked="" type="checkbox"/> Abramson, M.J., et al., "Allergen immunotherapy for asthma", <i>The Cochrane Library</i> , 1998 Jan; 1:1-32.						
<input checked="" type="checkbox"/> Akdis, Cezmi A., et al., "Epitope-specific T Cell Tolerance to Phospholipase A <sub>2</sub> in Bee Venom Immunotherapy and Recovery by IL-2 and IL-15 In Vitro", <i>The American Society for Clinical Investigations, Inc.</i> , 1996, Oct; 98(7):1676-1683.						
<input checked="" type="checkbox"/> Brazis, P., et al., "Stem Cell Factor Enhances IgE-Mediated Histamine and TNF-α Release From Dispersed Canine Cutaneous Mast Cells", <i>Vet Immunol. Immunopathol.</i> , 2000 Jun 30; 75(1-2):97-108.						
<input checked="" type="checkbox"/> Campbell, K.A., "Co-Crosslinking FcεRII/CD23 and B cell Surface Immunoglobulin Modulates B Cell Activation", <i>Eur J. Immunol.</i> 1992 Aug; 22(8):2107-12.						
<b>EXAMINER</b>			<b>DATE CONSIDERED</b>			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
<del>Castells, M., "Mast Cells: Molecular and Cell Biology", <i>The Journal of Asthma, Allergy and Immunology</i>, Vol.11:1-17, 1999.</del>		
<del>Delespesse, G., et al., "The Low-Affinity Receptor for IgE", <i>Immunol Rev.</i> 1992 Feb;125:77-97.</del>		
<del>Daeron, Marc., "Fcγ-RIIB as Potential Therapeutic Targets for Allergic Diseases", presented at the Annual Meeting of the American Academy of Allergy, Asthma &amp; Immunology, March 16-21, New Orleans, LA.</del>		
<del>Guo, C.B., et al., "Identification of IgE-bearing Cells in the Late-phase Response to Antigen in the Lung as Basophils", <i>Am J Respir. Cell Mol. Biol.</i>, 1994 Apr;10(4):384-90.</del>		
<del>Henz, B.M., et al., "[Urticaria. New developments and perspectives]., <i>Hautarzt</i> 2000 May;51(5):302-8.</del>		
<del>Hulett, Mark D., et al., "Fine Structure Analysis of Interaction of FcεRI with IgE", <i>Journal of Biological Chemistry</i>, Vol. 274, No. 19:13345-13352, 1999.</del>		
<del>Kawabori, S., et al., "Existence of c-kit Receptor-Positive, Tryptase-Negative, IgE-Neg Cells in Human Allergic Nasal Mucosa: A Candidate for Mast Cell Progenitor", <i>Int. Arch Allergy Immunol.</i> 1997 Jan;112:36-43.</del>		
<del>Kepley, C.L., et al., "Purification of Human Basophils by Density and Size Alone", <i>J. Immunol. Meth.</i>, 175:1-9, 1994.</del>		
<del>Kepley, C.L., et al., "The Identification and Partial Characterization of a Unique Marker for Human Basophils", <i>J. Immunol.</i>, 154, 6548-6555, 1995.</del>		
<del>Kepley, C.L., et al., "The Identification and Characterization of Umbilical Cord-Blood Derived Basophils", <i>J. Leukocyte Biol.</i>, 64:474-483, 1998.</del>		
<del>Kikutani, H., et al., "Molecular Structure of Human Lymphocyte Receptor for Immunoglobulin E", <i>Cell</i> 1986 Dec 5;47(5):657-65.</del>		
<del>Liénard, Hélène, et al., "Signal Regulatory Proteins Negatively Regulate Immunoreceptor-dependent Cell Activation", <i>The Journal of Biological Chemistry</i>, Vol 274, No. 45, Issue of November 5, pp. 32493-32499, 1999.</del>		
<del>Lin, Shih-Yao, et al., "Giving Inhibitory Receptors a Boost", <i>Science</i>, Vol. 291, Issue of January 19, pp. 445-446, 2001.</del>		
<del>Machiels, J.J., et al. "Significant Reduction of Nonspecific Bronchial Reactivity in Patients with <i>Dermatophagoides pteronyssinus</i>-sensitive Allergic Asthma under Therapy with Allergen-Antibody Complexes", <i>Am. Rev. Respir. Dis.</i>, Vol. 147, pp. 1407-1412, 1993.</del>		
<del>Machiels, J.J., et al. "Complexes of Grass Pollen Allergens and specific Antibodies Reduce Allergic Symptoms and Inhibit the Seasonal Increase of IgE Antibody", <i>Clin. Exp. Allergy</i>, Nov 20(6); 653-60, 1990.</del>		
<del>Machiels, J.J., et al., "Allergen-Antibody Complexes Can Efficiently Prevent Seasonal Rhinitis and Asthma in Grass Pollen Hypersensitive Patients", <i>Allergy</i>, 1991, 46, 335-348.</del>		
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<input checked="" type="checkbox"/> Machiels, J.J., et al., "Allergic Brochial Asthma Due to Dermatophagoides pteronyssinus Hypersensitivty Can Be Efficiently Treated by Inoculation of Allergen-Antibody Complexes", <i>J. Clin. Invest.</i> , Vol. 85, April 1990, 1024-1035.		
<input checked="" type="checkbox"/> Metcalfe, D.D., et al., "Mast Cell Ontogeny and Apoptosis", <i>Exp. Dermatol.</i> 1995: 4:227-230.		
<input checked="" type="checkbox"/> Mälgrom, H., et al., "Treatment of Allergic Asthma with Monoclonal Anti-IgE Antibody", <i>The New England Journal of Medicine</i> , Vol. 341, No. 26, 1966-1973, 1999.		
<input checked="" type="checkbox"/> Nakagawa, T., et al., "Immunotherapy of Allergic Diseases", <i>Int. Arch. Allergy Immunol</i> 102(2):117-20 1993.		
<input checked="" type="checkbox"/> Oliver, Janet M., et al., "Immunologically Mediated Signaling in Basophils and Mast Cells: Finding Therapeutic Targets for Allergic Diseases in the Human FcεR1 Signaling Pathway", <i>Immunopharmacology</i> 48, 269-281, 2000.		
<input checked="" type="checkbox"/> Osborne, Mark A., et al., "The Inositol 5'-Phosphatase SHIP Binds to Immunoreceptor Signaling Motifs and Responds to High Affinity IgE Receptor Aggregation", <i>The Journal of Biological Chemistry</i> , Vol. 271, No. 46, Issue of November 15, pp. 29271-29278, 1998.		
<input checked="" type="checkbox"/> Pivnyuk, V. I., et al., "Human Low-Affinity IgE Receptor: cDNA from Cell Line 1B and Its Expression in Peripheral Blood Cells", translated from <i>Molekulyarnaya Biologiya</i> , Vol 28, No. 1, pp. 840-845, July-August, 1994.		
<input checked="" type="checkbox"/> Schwartz, L., et al., "Development of Markers for Human Basophils and Mast Cells", <i>J. Allergy and Clin. Immunol.</i> , Vol. 94, No. 6, pp 1231-1240, 1994.		
<input checked="" type="checkbox"/> Sinclair, N.R. StC., "Why So Many Coinhibitory Receptors?", <i>Scand. J. Immunol.</i> 50, 1-13, 1999.		
<input checked="" type="checkbox"/> Suter, U., et al., "Expression of Human Lymphocyte IgE Receptor (FcεRII/CD23). Identification of the FcεRIIa Promoter and Functional Analysis in B Lymphocytes", <i>J. Immunol.</i> Nov 1; 143(9):3087-92, 1989.		
<input checked="" type="checkbox"/> Wang, M., et al., "Early IL-4 Production Driving Th2 Differentiation in a Human <i>in Vivo</i> Allergic Model is Mast Cell Derived", <i>Clin. Immunol.</i> Jan;90(1):47-54, 1999.		
<input checked="" type="checkbox"/> Yabuuchi, Shingo, et al., "Anti-CD23 Monoclonal Antibody Inhibits Germline Cε Transcription in B Cells", <i>International Immunopharmacology</i> 2, 453-461, 2002.		
<input checked="" type="checkbox"/> Yamashita, T., et al., "Expression Cloning of Complementary DNA Encoding Three Distinct Isoforms of Guinea Pig Fc Receptor for IgG1 and IgG2 <sup>1</sup> ", <i>J. Immunol.</i> Aug 15;151(4) pp. 2014-2023, 1993.		
<input checked="" type="checkbox"/> Yamashita, Y., et al., "Inhibitory and Stimulatory Functions of Paired Ig-Like Receptor (PIR) Family in RBL-2H3 Cells <sup>1</sup> ", <i>The Journal of Immunology</i> , 1998, 161: 4042-4047.		
<input checked="" type="checkbox"/> van Rossenberg, S.M., et al., "Ligand Recognition by CD22 {beta}: A Structure Function Study", <i>J. Biol. Chem</i> Jan 4, 2001.		
<input checked="" type="checkbox"/> Zhu, Daocheng, et al., "A Novel Human Immunoglobulin Fcγ-Fcε Bifunctional Fusion Protein Inhibits FcεRI-Mediated Degranulation", <i>Nature Medicine</i> Vol. 8, No. 5, pp. 518-521, May 2002.		
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